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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,026	04/13/2004	Stanton McHardy	16998 (PC25223A)	3372

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EXAMINER

PERLINGER, SARAH E

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/823,026

Applicant(s)

MCHARDY ET AL.

Examiner

Sarah E. Perlinger

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                             | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. Claims 1-29 are pending.
2. The Examiner contacted Arlene Musser via telephone on July 7, 2006 in regard to the following restriction requirement. A telephonic conference was tentatively scheduled with Ms. Musser for 10:00 am on July 10, 2006, however was canceled due to a telephonic request by Ms. Musser on July 10, 2006 for a written action in regard to the restriction requirement.

3. *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 9-10, 20, 28, drawn to a compound or a pharmaceutically acceptable salt, according to formula I wherein R1 and R2 are independently H, C1-C6 alkyl, -(CH<sub>2</sub>)<sub>k</sub>-aryl, or -(CH<sub>2</sub>)<sub>k</sub>-heteroaryl, classified in various class and subclasses depending on a species election. If this group is elected, election of a single disclosed species will also be required.
- II. Claims 1-7, 9-12, 15, 17-20, 28, drawn to a compound or a pharmaceutically acceptable salt according to formula I wherein R1 and R2 with the carbon to which they are attached, are connected to form a C3-C7 cycloalkyl group or a 4-7 membered carbocyclic group, wherein said cycloalkyl group is not fused to a C6-C14 aryl or 5-14 membered heteroaryl group, classified in class 546, subclass 184. If this group is elected, election of a single disclosed species will also be required.
- III. Claims 1-11, 13-14, 16-17, 20, 28, drawn to a compound or a pharmaceutically acceptable salt according to formula I wherein R1 and R2 with the carbon to

which they are attached, are connected to form a C3-C7 cycloalkyl group or a 4-7 membered carbocyclic group, wherein said cycloalkyl group is fused to a C6-C14 aryl or 5-14 membered heteroaryl group, classified in various class and subclasses depending on a species election. If this group is elected, election of a single disclosed species will also be required.

- IV. Claims 1-7, 9-10, 18, 20, 28, drawn to a compound or a pharmaceutically acceptable salt according to formula I wherein R1 and R2 with the carbon to which they are attached, are connected to form a heterocycloalkyl group which is not fused with a C6-C14 aryl or 5-14 membered heteroaryl, classified in various class and subclasses depending on a species election. If this group is elected, election of a single disclosed species will also be required.
- V. Claims 1-7, 9-10, 20, 28, drawn to a compound or a pharmaceutically acceptable salt according to formula I wherein R1 and R2 with the carbon to which they are attached, are connected to form a heterocycloalkyl group which is fused with a C6-C14 aryl or 5-14 membered heteroaryl, classified in various class and subclasses depending on a species election. If this group is elected, election of a single disclosed species will also be required.
- VI. Claims 21-24, drawn to a method of treating in a mammal, in need thereof, a disease state, disorder or condition mediated by an opioid receptor or receptors, class 514, various subclasses depending on species election. If this group is elected, a further election of a single disclosed compound to treat a single

disclosed disease will also be required. Further restriction based on species election will also be required.

- VII. Claims 25-27, drawn to use of a compound according to claim 1 in the manufacture of a medicament for the treatment of a mammal, classified in various class and subclasses depending on a species election. If this group is elected, election of a single disclosed species of claim 1 will also be required.
- VIII. Claim 29, drawn to a method for obtaining an image of opioid receptors in a mammalian subject, classified in class 424, subclass 9.3. If this group is elected, election of a single disclosed species of claim 28 will also be required.

The compounds of groups I-V differ in elements, bonding arrangements and chemical structure to such an extent that a reference anticipating any one group would not render the other group obvious, thus unpatentability of any group would not necessarily imply unpatentability of another group. The search for each diverse core structure as delineated is not coextensive with each other and will constitute an enormous burden.

Inventions VI-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions VI-VIII are not disclosed as capable of use together and they all have different effects. For example, group VI treats disease states, disorders or conditions in a mammal while group VIII obtains an image of opioid receptors in mammalian subjects. Group VI is drawn to a pharmaceutical treatment while group VIII is drawn to an imaging process.

Inventions I-V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of treating a disease state, disorder or condition mediated by an opioid receptor or receptors can be practiced with another materially different product. For example, hyperforin, a compound found in St. John's Wart, has been used to treat depression (see Watkins et al., *Biochemistry*, 2003, 42, 1430-1438).

Inventions I-V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process than the process of group VIII. For example, the products of groups I-V can be used to obtain an image of an opioid receptor in a mammalian subject.

Inventions I-V and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process than the process of group VIII. For example, the products of groups I-V can be used to manufacture a pharmaceutical composition.

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Because these inventions are independent and distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent and distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Should applicant traverse on the ground that the groups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. In the instant case, applicants will not have patentability over any of the claims because US 20050222204 anticipated group II (see claim 1). The reference qualifies as prior art under 102(e).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Sarah E. Perlinger, whose telephone number is (571) 272-5574. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Cecilia Tsang, can be reached at (571) 272-0562. The fax number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
07/10/2006

  
Celia Chang  
Primary Examiner  
Art Unit 1625